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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,133	03/29/2006	Filippa Brugliera	18612	2581

23389 7590 12/09/2008

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ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,133	BRUGLIERA ET AL.	
	Examiner	Art Unit	
	VINOD KUMAR	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/2/08 & 10/15/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-37* is/are pending in the application.

4a) Of the above claim(s) *36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's response (10/10/2008) to notice of non-compliant amendment mailed in the paper of September 11, 2008 is acknowledged.

Applicant's election with traverse of Group I, and SEQ ID NOs: 11 and 12 in the reply filed on June 2, 2008 is acknowledged. Applicant's amendment filed in the paper of June 2, 2008 is also entered.

Claims 1-27 are cancelled.

Claims 28-37 are newly added claims.

Newly added claims 28-35 fall within the scope of the elected invention.

Newly added claims 36-37 fall within the scope of non-elected invention (Group V), and are thus withdrawn from the present examination.

The traversal is on the ground(s) that the two molecules SEQ ID NO: 9/10 and SEQ ID NO: 11/12, represent two pansy clones encoding F3'5'H which are related to each other and thus should be examined together (response, pg 7, lines 8-13). This is not found persuasive because the technical feature linking different inventions does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Applicants are reminded that different nucleotide sequences and amino acid sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute different inventive concepts. Accordingly, these inventions are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Thus restriction requirement is still deemed proper and is therefore made FINAL.

Newly added claims 36-37 and SEQ ID NOs: 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 2, 2008. Accordingly, newly added claims 28-35 in conjunction with elected SEQ ID NOs: 11 and 12 are examined on merits in the present Office action.

This application contains claims 36-37, and SEQ ID NOs: 9 and 10 drawn to inventions nonelected with traverse in the reply filed on June 2, 2008. A complete reply to the final rejection must include cancellation of nonelected claim or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. Initialed and dated copy of Applicant's IDS form 1449 filed in the paper of September 27, 2007 is attached to the instant Office action. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

3. The listing of references in the specification (pages 129-133) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Priority

4. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of Application No. Australia 2002951088, filed August 30, 2002 and Application No. Australia 2002952835, filed September 16, 2002 have been received.

Claim Objections

5. Claims 28, 31-33 and 34 are objected to because of the following informalities:

Claim 28 is objected for having non-elected SEQ ID NOs: 9 and 10.

In claim 28, it is suggested to change part (iii) to --a nucleotide sequence as set forth in SEQ ID NO: 11--.

Claims 31 and 34 are objected for reciting “CaMV35s”. It is suggested to replace “CaMV35s” with --CaMV 35S--.

Claim 32 is objected for having improper article before “nucleic acid” in line 1. It is suggested to change “a” to --the--.

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 32 would require an operably linked promoter for the nucleic acid sequence to express in the genetically modified plant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation “high stringency conditions” in line 2 of part (iv), which is confusing, since it is unclear what level of stringency is encompassed by “high stringency conditions”. Page 31, line 10 through line 28 of the specification gave examples of “high stringency conditions” but did not define the term "high stringency conditions". The temperature and washing conditions encompassed by the recitation “high stringency conditions” are not defined. One of skilled in the art would not know what specific conditions are meant by “high stringency conditions”. The metes and bounds of the claim are indefinite without knowing the exact conditions. One of skill in the art would not be reasonably apprised of the scope of the invention.

Dependent claims 29-35 are also rejected because they fail to overcome the deficiency of claim 28.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "a progeny thereof", which is confusing, since it is unclear whether the progeny comprises the nucleic acid molecule. It is suggested that the recitation, --, wherein said rose progeny comprises said nucleic acid molecule-- be inserted at the end of claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleotide sequence encoding a flavonoid 3', 5' hydroxylase (F3'5'H) as set forth in SEQ ID NO: 12, a genetic construct or a genetically modified plant comprising said nucleotide sequence, does not reasonably provide enablement for (a) a nucleotide sequence having 80% sequence identity to SEQ ID NO: 11, (b) a nucleotide sequence encoding an amino acid having 90% similarity to SEQ ID NO: 12, (c) a nucleotide sequence capable of hybridizing under high stringency conditions to the nucleotide sequence of SEQ ID NO: 11, and (d) a genetically modified plant or progeny comprising "a complementary" of a nucleotide sequence encoding the F3'5'H protein of SEQ ID NO: 12. The specification does not enable any person skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a flavonoid 3', 5' hydroxylase (F3'5'H), said nucleotide sequence encoding an amino acid sequence having 90% similarity to SEQ ID NO: 12, capable of hybridizing under high stringency conditions to SEQ ID NO: 11 or its complement form, or comprising a sequence having 80% identity to SEQ ID NO: 11, or wherein said nucleic acid molecule comprises CaMV 35S promoter operably linked to it, a genetic construct or a genetically modified plant or progeny thereof comprising said nucleic acid molecule comprising said promoter, or wherein said genetically modified plant is rose or a progeny thereof.

Claim 28 is directed to a nucleotide sequence encoding an amino acid sequence having 90% sequence similarity to SEQ ID NO: 12.

Claim 28 is also directed to a nucleotide sequence having 80% sequence identity to SEQ ID NO: 11.

The instant specification, however, provides guidance for how to make and use a nucleotide sequence (SEQ ID NO: 11) isolated from *Viola spp*. which encodes F3'5'H protein of SEQ ID NO: 12. The specification teaches using said nucleotide sequence in a method of producing transgenic carnations having modified petal (flower part) pigmentation compared to a control plant. See pgs 93-95; pgs 111-114, tables 11-12.

The instant specification fails to provide guidance on how to make nucleic acid sequences encoding a functional F3'5'H protein having 90% sequence similarity to SEQ ID NO: 12.

Making all possible single amino acid substitutions in an 506 amino acid long protein like that encoded by SEQ ID NO: 11 would require making and analyzing 19^{506} nucleic acid sequences; these proteins would have 99.8% identity to SEQ ID NO: 12. Because nucleic acid sequences encoding proteins with 90% sequence identity to the 506 amino acid long SEQ ID NO: 12 would encode proteins with 50 amino acid substitutions relative to SEQ ID NO: 12, many more than 19^{506} nucleic acid sequences would need to be made and analyzed. This analysis is based on 90% identity to SEQ ID NO: 12, implying that the recitation "90% similarity to SEQ ID NO: 12" would encompass higher than 50 amino acid substitutions relative to SEQ ID NO: 12.

The instant specification also fails to provide guidance on how to make nucleic acid sequences having 80% sequence identity to SEQ ID NO: 11, and which encode a F3'5'H protein.

Nucleotide sequences with 80% identity to SEQ ID NO: 11 would have 356

substitutions relative to 1782 nucleotides of SEQ ID NO: 11; these encompass nucleotide sequences encoding protein(s) having 356 amino acid substitutions relative to SEQ ID NO: 12. These protein(s) would exhibit 29% identity to instant SEQ ID NO: 12.

The specification at page 39, lines 1-8, says:

> Functional derivative means any single or multiple (1-20) amino acid substitutions, deletions, and/or insertions relative to the naturally occurring enzyme and which retains F3'5'H activity.

The specification does not provide guidance in the specification with respect to making amino acid substitutions in F3'5'H protein of SEQ ID NO: 12.

Thus, from the guidance in the specification, it would appear that a large number of amino acids in SEQ ID NO: 12 could be substituted with any other amino acid. The instant specification fails to provide guidance for which amino acids of SEQ ID NO: 12 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain F3'5'H activity of the altered protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein having F3'5'H activity.

Making amino acid substitutions in SEQ ID NO: 12 protein is unpredictable. While it is known that many amino acid substitutions, additions or deletions are generally possible in any given protein the positions within the protein's sequence where such amino acid changes can be made with a reasonable expectation of success (without altering protein function) are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or

regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These regions can tolerate only relatively conservative substitutions or no substitutions (see for example, Wells, Biochemistry 29:8509-8517, 1990, see pages 8511-8512, tables 1-2; Ngo et al., pp. 492-495,1994, see page 491, 1st paragraph).

Also see Guo et al. (PNAS, 101: 9205-9210, 2004, see page 9205, abstract; page 9206, table 1; page 9208, figure 1) who teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as the claims encompass more than a single amino acid changes of the polypeptide defined in SEQ ID NO: 12.

Also see, Keskin et al. (Protein Science, 13:1043-1055, 2004, see page 1043, abstract) who teach that proteins with similar structure may have different functions. Furthermore, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000, page 992, 2nd paragraph bridging columns 1 and 2) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions.

Thus, making and analyzing proteins with a large number of amino acid changes that also have F3'5'H would require undue experimentation.

Additionally, claim 32 is directed to a genetically modified plant or progeny comprising expression of the nucleic acid molecule encoding SEQ ID NO: 12 which

results in altered flower color. The specification does not teach making a genetically modified plant having said nucleic acid molecule in any manner other than transforming (introducing and overexpressing) a plant with a nucleotide acid sequence encoding the F3'5'H protein of SEQ ID NO: 12. The specification does not provide guidance on co-factors, or positive regulators of the nucleic acid sequence encoding SEQ ID NO: 12, for example that makes SEQ ID NO: 12 to overexpress to produce a plant with altered flower color. The specification provides no guidance on up-stream regulatory factors, for example, that may be necessary in stimulating the overexpression of SEQ ID NO: 12. In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how a plant with an altered flower color could have been produced by the overexpression of SEQ ID NO: 12 without transforming the plant with a nucleotide sequence encoding SEQ ID NO: 12.

Additionally, claims 32-35 are directed to a genetically modified plant or progeny thereof, comprising a complimentary sequence of a nucleotide sequence encoding the F3'5'H protein of SEQ ID NO: 12. Since complimentary sequence of SEQ ID NO: 11 would read on a sequence which would either encode no protein or encode a protein unrelated in function to SEQ ID NO: 12. A complementary sequence also reads on 2-mer long sequence of SEQ ID NO: 11.

Given this, the expression of said complementary sequence in a genetically modified plant would not result in the expression of F3'5'H protein. In the absence of guidance, undue experimentation would have been required by a skilled artisan how to use said plants that show the expression of complementary sequence of a nucleotide sequence encoding SEQ ID NO: 12.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleotide sequences encoding proteins having 90% sequence similarity to SEQ ID NO: 12, and nucleotide sequences having 80% sequence identity to SEQ ID NO: 11, for obtaining genetically modified plants having altered flower color. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claim 28 is directed to a nucleotide sequence capable of hybridizing under high stringency conditions to SEQ ID NO: 11 or its complementary form.

Page 31, line 10 through line 28 of the specification gave examples of "high stringency conditions" but did not define the term "high stringency conditions". The temperature and washing conditions encompassed by the recitation "high stringency conditions" are not defined. One of skilled in the art would not know what specific conditions are meant by "high stringency conditions".

This would imply that any nucleotide sequence would hybridize to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 12. This is because the high stringency conditions of hybridization recited in the claims would encompass hybridization of a nucleic acid sequence that is unrelated to a nucleotide acid sequence encoding SEQ ID NO: 12.

State of the art related to DNA hybridization suggests that in order to prevent hybridization of unrelated nucleic acid sequence(s) to a target sequence, hybridization and subsequent washing conditions must be highly stringent. For example,

hybridization under conditions of 0.1 - 1.0x SSC, 50% formamide and 50 °C for 24 hours, followed by 2 washes in 0.1% SDS, 0.1x SSC at 65 °C for 25-30 minutes each is considered highly stringent condition that would not allow hybridization of unrelated nucleic acid sequences to the target sequence. See for example, Maniatis et al. (Molecular Cloning: A Laboratory Manual, Cold Spring Harbor Laboratory, 1982; see in particular pages 387-389).

In the absence of adequate guidance, undue experimentation would have been required by one skilled in the art at the time the claimed invention was made to determine how to use said unrelated sequences in obtaining F3'5'H activity in the encoded protein(s).

In the absence of guidance, undue experimentation would have been required by a skilled artisan to determine how to use genetic constructs or genetically modified plant comprising said unrelated sequences in obtaining altered flower color.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids that hybridize under high stringency conditions to a nucleotide sequence encoding SEQ ID NO: 12.

As the specification does not describe the transformation of any plant with a gene comprising a promoter operably linked with a nucleotide sequence having 80% sequence identity to SEQ ID NO: 11, a nucleotide sequence encoding a polypeptide having 90% similarity to SEQ ID NO: 12, or a nucleotide sequence (unrelated) hybridizing under high stringency conditions to a nucleotide sequence encoding F3'5'H protein of SEQ ID NO: 12, undue trial and error experimentation would be required to

screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those which produce functional F3'5'H protein that can alter flower color, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

8. Claims 28-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a flavonoid 3', 5' hydroxylase (F3'5'H), said nucleotide sequence encoding an amino acid sequence having 90% similarity to SEQ ID NO: 12, capable of hybridizing under high stringency conditions to SEQ ID NO: 11 or its complement form, or comprising a sequence having 80% identity to SEQ ID NO: 11, or wherein said nucleic acid molecule comprises CaMV 35S promoter operably linked to it, a genetic construct or a genetically modified plant or progeny thereof comprising said nucleic acid molecule comprising said promoter, or wherein said genetically modified plant is rose or a progeny thereof.

The essential feature of claim 28 is a nucleotide sequence encoding an amino acid sequence having 90% sequence similarity to SEQ ID NO: 12.

The essential feature of claim 28 is also a nucleotide sequence having 80% sequence identity to SEQ ID NO: 11.

The instant specification, however, describes a nucleotide sequence (SEQ ID NO: 11) isolated from *Viola spp*. which encodes F3'5'H protein of SEQ ID NO: 12. The specification also describes expressing said nucleotide sequence in a transgenic plant which exhibits modified petal (flower part) pigmentation compared to a control plant. See pgs 93-95; pgs 111-114, tables 11-12.

The specification also describes amino acid sequences having at least about 90% identity to SEQ ID NO: 12 as the sequences having additions, deletions, additions and/or inversions of one or more amino acids in the amino acid sequence of SEQ ID NO: 12. However, the specification does not describe the structure and function for said sequences.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of a F3'5'H protein of SEQ ID NO: 12. Thus, Applicant's broadly claimed genus encompasses structures whose function is unrelated to the instantly claimed SEQ ID NO: 11 encoding the FMT protein of SEQ ID NO: 12.

The only species described in the specification is SEQ ID NO: 11, which encodes SEQ ID NO: 12.

Nucleotide sequences encoding structures (proteins) having about 90%

sequence similarity to instant SEQ ID NO: 12 are no described, and thus their function is unknown.

Nucleotide sequences that have about 80% sequence identity to instant SEQ ID NO: 11 are not described, and thus their function is unknown.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NOs: 11 and 12 are insufficient to describe the claimed genus.

The essential feature of claim 28 is a nucleotide sequence which is capable of hybridizing under high stringency conditions to a nucleotide sequence of SEQ ID NO: 11.

Page 31, line 10 through line 28 of the specification gave examples of “high stringency conditions” but did not define the term "high stringency conditions". The temperature and washing conditions encompassed by the recitation “high stringency conditions” are not defined. One of skilled in the art would not know what specific conditions are meant by “high stringency conditions”.

This would imply that <u>any</u> nucleotide sequence would hybridize to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 12. This is because the high stringency conditions of hybridization recited in the claims would encompass

hybridization of a nucleic acid sequence that is unrelated to a nucleotide acid sequence encoding SEQ ID NO: 12.

The specification does not describe the structure and function of said unrelated hybridizing sequences.

There is no description of the structure required for the recited function, and no description of the necessary and sufficient elements of a nucleic acid sequence which encodes SEQ ID NO: 12.

The only species described in the specification is SEQ ID NO: 11, which encodes SEQ ID NO: 12.

Structures that would hybridize under high stringency conditions to a nucleotide sequence (including SEQ ID NO: 11) encoding SEQ ID NO: 12 are not described, and thus their function is unknown.

Structures that would hybridize under high stringency conditions to a nucleotide sequence which is “a complementary sequence” of SEQ ID NO: 11 are not described, and thus their function is unknown. It is important to note “a complimentary sequence” recited in claim 28 would read on a genus of sequences having 2 nucleotides of SEQ ID NO: 11.

One of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 11 and its encoded protein of SEQ ID NO: 12 are insufficient to describe the claimed genus.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 28-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Holton et al. (WIPO, WO 94/28140, Published 8 December, 1994; Applicant's IDS).

Claims are broadly drawn to an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a flavonoid 3', 5' hydroxylase (F3'5'H), said nucleotide sequence encoding an amino acid sequence having 90% similarity to SEQ ID NO: 12, capable of hybridizing under high stringency conditions to SEQ ID NO: 11 or its complement form, or comprising a sequence having 80% identity to SEQ ID NO: 11, or wherein said nucleic acid molecule

comprises CaMV 35S promoter operably linked to it, a genetic construct or a genetically modified plant or progeny thereof comprising said nucleic acid molecule comprising said promoter, or wherein said genetically modified plant is rose or a progeny thereof.

Holton et al. disclose a nucleic acid sequence encoding a flavonoid 3',5' hydroxylase. The reference also discloses making transgenic plants (including rose) comprising transformation of plants with a genetic construct which comprises a nucleic acid sequence encoding said F3'5'H, and wherein said nucleic acid sequence is operably linked to a promoter (e.g. CaMV 35S). The reference also discloses that said transformed plants and progenies derived thereof exhibited altered flower color. The reference also discloses detecting delphinidin or delphinidin based molecules in a rose petal of said transgenic plant as measured by a chromatographic technique. See in particular, abstract; claims 1-29; figures 1-9; examples 1-24; pg 22, lines 15-22.

This rejection is made because Office contends that hybridization conditions recited in part (iv) of claim 28 would encompass hybridization of nucleic acid sequence(s) that are unrelated (low homology sequences) to SEQ ID NO: 11. Page 31, line 10 through line 28 of the specification gave examples of "high stringency conditions" but did not define the term "high stringency conditions". The temperature and washing conditions encompassed by the recitation "high stringency conditions" are not defined. One of skilled in the art would not know what specific conditions are meant by "high stringency conditions".

This would imply that <u>any</u> nucleotide sequence would hybridize to a nucleotide sequence encoding the polypeptide of SEQ ID NO: 12. This is because the high stringency conditions of hybridization recited in the claims would encompass

hybridization of a nucleic acid sequence that exhibits low homology to SEQ ID NO: 11 but encodes a functional F3'5'H protein.

This rejection is also made because Office contends that the recitation "a complement" in parts (i) and (iv) of claim 28 would also read on a nucleotide sequence comprising 2 nucleotide sequence of a nucleotide sequence (SEQ ID NO: 11) encoding instant SEQ ID NO: 12.

Accordingly, Holton et al. anticipated the claimed invention.

Conclusions

10. Claims 28-35 are rejected.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)272-0975. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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/Vinod Kumar/
Examiner, Art Unit 1638